

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A,  
INC.,

Plaintiff

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 19-2216-RGA

MEMORANDUM OPINION

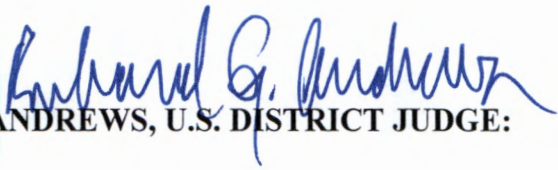
Francis DiGiovanni, Thatcher A. Rahmeier, FAEGRE DRINKER BIDDLE & REATH LLP, Wilmington, DE; Edgar H. Haug, Porter F. Fleming (argued), Jonathan A. Herstoff, Camille Y. Turner, HAUG PARTNERS LLP, New York, NY,

Attorneys for Plaintiff.

Kenneth L. Dorsney, Cortlan S. Hitch, MORRIS JAMES LLP, Wilmington, DE; Stu Williams, Michael S. Sommer (argued), Jessica L. Margolis, Sheryl Shapiro Bassin, Cassie L. Black, WILSON SONSINI GOODRICH & ROASTI, P.C., New York, NY; Ellie F. Steiner, WILSON SONSINI GOODRICH & ROASTI, P.C., San Diego, CA,

Attorneys for Defendant.

September 17, 2023



ANDREWS, U.S. DISTRICT JUDGE:

Before the Court is Defendant Mylan's Motion for Summary Judgment and to Exclude Expert Testimony. (D.I. 216). I have considered the parties' briefing (D.I. 217, 222, 226), and I heard oral argument on August 15, 2023. (D.I. 242). For the reasons set forth below, the motion for summary judgment is GRANTED and the motion to exclude expert testimony is DISMISSED as MOOT.

## I. BACKGROUND<sup>1</sup>

Plaintiff Takeda manufactures and markets Colcrys, a branded version of the drug colchicine, which is approved by the Food and Drug Administration (FDA) to treat and prevent gout flares and familial Mediterranean fever. (D.I. 2 at ¶ 15). Takeda has seventeen patents listed for Colcrys in the FDA's "Orange Book." (*Id.* at ¶¶ 22–44). Between 2013 and 2018, Takeda sued a number of generic manufacturers that submitted Abbreviated New Drug Applications (ANDA) to the FDA. (*Id.* at ¶¶ 60–61). Defendant Mylan filed an ANDA with the FDA in 2016, seeking approval of a generic colchicine product. (*Id.* at ¶ 45). Based on that filing, Takeda sued Mylan for infringement of its seventeen Colcrys patents. *Takeda Pharmaceuticals U.S.A., Inc. v. Mylan Pharmaceuticals Inc.*, No. 16-cv-987-RGA (D. Del.). The parties settled their lawsuit on November 7, 2017. (D.I. 218, Ex. 1, "Settlement Agreement.")

As part of that settlement, the parties signed a License Agreement, which allows Mylan to sell a generic colchicine product after a certain date.<sup>2</sup> (D.I. 218, Ex. 2, "Agreement."). Section 1.2

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<sup>1</sup> The first four paragraphs of this section is essentially the same as what I wrote in connection with my preliminary injunction decision. *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms., Inc.*, 2020 WL 419488 at \*1 (D. Del. Jan. 27, 2020).

<sup>2</sup> The dates are extremely confidential, and the exact dates are irrelevant to the decision. Thus, I do not need to disclose them in this opinion.

provides several situations, however, in which Mylan is permitted to launch its generic competitor before that date. Section 1.2(d) states that Mylan is entitled to launch a generic at:

The date that is [a specified time period] after the date of a Final Court Decision (as defined in Exhibit A) holding that all unexpired claims of the Licensed Patents that were asserted and adjudicated against a Third Party are either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable.

(*Id.*). Exhibit A defines a “Final Court Decision” as “the entry by a federal court of a final judgment from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.” (*Id.*). The “Licensed Patents” include the seventeen Colcrys Orange Book patents Takeda had asserted against Mylan. (*Id.*). A “Third Party” is a “Person other than a Party or an Affiliate of a Party.” (*Id.*).

According to Mylan, Section 1.2(d) was triggered by my decision in a separate case, *Takeda Pharms., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-cv-1268-RGA (D. Del.). In that litigation, Takeda asserted eight of its Colcrys patents against West-Ward, but, during summary judgment briefing, it indicated it was “willing” to dismiss five of them (*id.*, D.I. 361 at 1, n.2), which it did “with prejudice” a few weeks later (*id.*, D.I. 376). I “so ordered” the dismissal. I granted summary judgment of non-infringement on the three remaining patents. *Takeda Pharms., U.S.A., Inc. v. West-Ward Pharm. Corp.*, 2018 WL 6521922 (D. Del. Dec. 12, 2018).

On October 28, 2019, Mylan notified Takeda that it planned to “immediately start selling” a generic colchicine product “pursuant to the Parties’ November 7, 2017 license agreement (Section 1.2(d)).” (D.I. 15, Ex. 11). Takeda sued Mylan for patent infringement and breach of contract. (D.I. 2). Takeda filed a motion for a preliminary injunction, seeking to enjoin Mylan from commercially manufacturing, offering to sell, or selling its generic colchicine product within the United States. (D.I. 12). Mylan moved to dismiss Takeda’s suit. (D.I. 71).

After full briefing and oral argument, I issued an order denying Takeda's motion for preliminary injunction. (D.I. 114). I held that Takeda “failed to show it is likely to succeed on the merits or that it will suffer irreparable harm.” (*Id.* at 1). The Federal Circuit affirmed my denial of a preliminary injunction. *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, 967 F.3d 1339 (Fed. Cir. 2020). Following the Federal Circuit’s decision affirming my denial of a preliminary injunction, I denied Mylan’s motion to dismiss because I do not think the decision established the law of the case that the agreement is unambiguous. (D.I. 154). Mylan moved for reconsideration, which I denied for similar reasons. (D.I. 162).

I subsequently bifurcated this action so that we could first resolve Takeda’s one breach of contract claim. (D.I. 198). I thought the breach of contract claim would likely fail, and, if that proved out, the massive expenses associated with twenty-two asserted patents could be avoided. The parties have completed fact and expert discovery on related to the breach of contract claim. Mylan subsequently filed the pending motion.

## **II. LEGAL STANDARD**

“The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” FED. R. CIV. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those “that could affect the outcome” of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). “[A] dispute about a material fact is ‘genuine’ if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party.” *Id.* The burden on the moving

party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: “(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . .” FED. R. CIV. P. 56(c)(1). The non-moving party's evidence “must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance.” *Williams*, 891 F.2d at 460–61.

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

### III. DISCUSSION

Mylan contends that summary judgment should be granted because the language of the Agreement is unambiguous and permits Mylan to launch its generic colchicine product. (D.I. 217 at 13–18). Mylan further argues that even if I were to find the provision ambiguous, the extrinsic evidence supports Mylan's interpretation. (*Id.* at 18–22). Takeda responds that its interpretation of



the Agreement is the only reasonable interpretation given the context the Agreement was drafted under – namely, the Hatch-Waxman Act – and the competing interpretations indicate ambiguity that must be resolved by a jury.<sup>3</sup> (D.I. 222 at 11–20).

#### **A. Preliminary Injunction Decision**

As an initial matter, the parties disagree as to whether I can consider the prior rulings from the preliminary injunction stage. Takeda argues that the preliminary injunction ruling is now “stale.” (D.I. 222 at 10). Not so. My orders denying Mylan’s motions to dismiss and for reconsideration merely pointed out that the law of the case was not applicable because both I and the Federal Circuit applied the preliminary injunction standard, which involves “preliminary” determinations about likelihood of success on the merits, not final determinations about success. (D.I. 162) (citing *Association of New Jersey Rifle & Pistol Clubs Inc. v. Attorney General New Jersey*, 974 F.3d 237, 245 n.6 (3d Cir. 2020)).

As Mylan points out, “Findings need not be deemed law of the case in order to be instructive.” (D.I. 226 at 2). Certainly, the standards for prevailing on preliminary injunction and summary judgment are different. This does not mean, however, that the reasoning applied in denying Takeda’s motion for a preliminary injunction cannot bear on Mylan’s motion for summary judgment now, particularly where similar issues are presented. I also note that Takeda has abandoned most of the arguments it made at the preliminary injunction stage, and there is almost nothing in the Federal Circuit’s decision with which Takeda takes issue. Indeed, at argument, the only objection that Takeda could articulate in response to my questioning is that footnote 5 of Federal Circuit decision took too narrow of a view of what an “adjudication” includes. (D.I. 242

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<sup>3</sup> Takeda did not move for summary judgment on the breach of contract claim. It does, however, assert that if the agreement is unambiguous, I should consider granting it summary judgment. (D.I. 222 at 2, 30).

at 13:10-14:12). Takeda's position is that an "adjudication" includes not only an adjudication on the merits (in the sense of a ruling) but also resolutions that count as an "adjudication" for any purpose, including claim preclusion.

### **B. The License Agreement**

In Delaware<sup>4</sup>, "the proper interpretation of [contract] language is a question of law." *Allied Capital Corp. v. GC-Sun Holdings, L.P.*, 910 A.2d 1020, 1030 (Del. Ch. 2006). "[B]ecause Delaware adheres to an objective theory of contracts, the contract's construction should be that which would be understood by an objective, reasonable third party." *Exelon Generation Acquisitions, LLC v. Deere & Co.*, 176 A.3d 1262, 1267 (Del. 2017). Each term and provision should be given effect, "so as not to render any part of the contract mere surplusage," and the interpretation should not render a term or provision "meaningless or illusory." *Osborn ex rel. Osborn v. Kemp*, 991 A.2d 1153, 1159 (Del. 2010) (citation omitted). "When the contract is clear and unambiguous, we will give effect to the plain-meaning of the contract's terms and provisions. On the contrary, when we may reasonably ascribe multiple and different interpretations to a contract, we will find that the contract is ambiguous." *Id.* at 1159-60. "The determination of ambiguity lies within the sole province of the court." *Id.* at 1160.

The parties' main dispute concerns the phrase "were asserted and adjudicated." The critical issue here stems from how the parties interpret the phrase "and adjudicated."

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<sup>4</sup> Section 9 of the Settlement Agreement states, "This Settlement Agreement shall be governed and interpreted in accordance with the law of the State of Delaware without regard to conflicts of law principles." (D.I. 218, Ex. 1 at 7). Section 5 of the License Agreement states, "This License Agreement shall be governed and interpreted in accordance with the law of the State of Delaware without regard to conflicts of law principles." (D.I. 218, Ex. 2 at 11). Neither party disputes that Delaware law applies.

Mylan reads the term in conjunction with “asserted,” such that Section 1.2(d) is triggered when “all unexpired claims” that “were asserted and adjudicated against a Third Party are...not infringed,” meaning the clause requires a Final Court Decision<sup>5</sup> only for the claims that were both asserted *and* adjudicated. Under Mylan’s interpretation, the five patents that were dismissed with prejudice in *West-Ward* were not adjudicated, and once they were dismissed, were no longer asserted. Therefore, Mylan’s argument goes, the five dismissed patents are not relevant for the purposes of Section 1.2(d) because only claims from the remaining three patents were “asserted and adjudicated.”

Takeda splits Section 1.2(d) into the following decision tree:

- [a specified time period] after a Final Court Decision *holding* that
  - all unexpired claims of the Licensed Patents that
    - i. *were asserted and*
    - ii. *adjudicated* against a Third Party
  - are either
    - a. not infringed, or
    - b. any combination of not infringed and invalid or unenforceable

(D.I. 222 at 11). Takeda then individually analyzes the terms “were asserted,” “and adjudicated,” and “holding.” According to Takeda, claims from all eight patents in *West-Ward* were asserted and adjudicated, meaning all eight patents had to be the subject of a holding in order to trigger Section 1.2(d). Under Takeda’s interpretation, the five dismissed patents were “adjudicated” because they were dismissed “with prejudice” but were not subject to a holding of non-infringement, meaning Section 1.2(d) could not have been triggered.

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<sup>5</sup> The parties do not dispute that my summary judgment decision in *West-Ward* was a “Final Court Decision.” (D.I. 217 at 10).



I agree with Mylan's interpretation for the reasons set forth below. A plain reading of the Agreement makes clear that the final judgment in the *West-Ward* litigation triggered Section 1.2(d).

**1. “were asserted and adjudicated”**

Takeda first contends that claims from all eight patents were asserted because they were pled in the operative complaint, were the subject of discovery, and were included in the summary judgment motion in *West-Ward*. Mylan argues that once the five patents were dismissed, those claims were no longer asserted, and recategorized as “unasserted” patents. (D.I. 217 at 17). I agree with Takeda that all eight patents were asserted in the *West-Ward* litigation. (*See* D.I. 114 at 4).

Next, Takeda argues that the five dismissed patents were adjudicated because a dismissal with prejudice functions as an adjudication on the merits. (D.I. 222 at 13–14). To support this contention, Takeda cites to various cases which it argues hold that a dismissal with prejudice is an adjudication on the merits. In particular, Takeda analyzes the Supreme Court's reasoning in *Semtek Int'l Inc. v. Lockheed Martin Corp.*, noting that the Court relied on Wright & Miller for the contention that “with prejudice” is a shorthand for “an adjudication on the merits.” (D.I. 222 at 14) (citing *Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 505 (2001)).

Takeda reads too much into the Supreme Court's analysis in *Semtek*. The Court in *Semtek* specifically discussed claim preclusion in its analysis of Rule 41, where a “dismissal on the merits and with prejudice” has claim-preclusive effect. *Semtek*, 531 U.S. at 505. The citations in *Semtek* to Wright & Miller are specific to claim preclusion. *Id.* (citing 18 Wright & Miller § 4435 (under Chapter 13. Res Judicata); 9 *id.*, § 2373, at 396, n.4 (commenting specifically on the claim-preclusive effect of a dismissal without prejudice)). In fact, Wright & Miller explicitly states, “A stipulated dismissal with prejudice operates as an adjudication on the merits for claim-preclusion

purposes, but ordinarily should not of itself count as the actual adjudication of any issue.” *Id.* at § 4435; *see also Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1373 (Fed. Cir. 2013). Each of Takeda’s other cited cases also discusses dismissal with prejudice in the context of claim preclusion.<sup>6</sup>

At oral argument, Takeda urged that the term “adjudication” in the Agreement includes dismissals that would invoke claim preclusion. (D.I. 242 at 13:13-14:7). Nothing in the Agreement, however, suggests that the parties contemplated “adjudication” in the context of claim preclusion. Further, neither party is asserting claim preclusion in this case, making whether claim preclusion “operates as” an “adjudication” in that narrow context irrelevant.<sup>7</sup> Instead, the plain meaning of the term makes clear that judicial analysis and a resolution is required for a claim to be “adjudicated.” Black’s Law Dictionary defines “adjudication” as “[t]he legal process of resolving a dispute; the process of judicially deciding a case.” BLACK’S LAW DICTIONARY (11th ed. 2019). As the Federal Circuit pointed out, the plain language of Section 1.2(d) describes a “holding,” which “contemplates an adjudication that is a substantive decision resolving an issue of

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<sup>6</sup> *See* D.I. 222 at 13–14, n. 8 (citing *Papera v. Pennsylvania Quarried Bluestone Co.*, 948 F.3d 607, 611 (3d Cir. 2020) (defining a dismissal with prejudice as an adjudication on the merits for claim preclusion purposes); *Chavez v. Dole Food Co.*, 836 F.3d 205, 210 n.2 (3d Cir. 2016) (noting that the label “with prejudice” “signifies” an adjudication on the merits to bar further litigation of the claim); *Highway Equip. Co. v. FECO, Ltd.*, 469 F.3d 1027, 1035 (Fed. Cir. 2006) (stating that a dismissal with prejudice is a judgment on the merits to determine the prevailing party for purposes of costs because it “terminates any claims the plaintiff may have had against the defendants arising out of this set of operative facts.” (citations omitted))).

<sup>7</sup> Courts also distinguish claim preclusion, which does not require actual litigation, from issue preclusion, which applies to issues actually litigated, or adjudicated. *See Levi Strauss*, 719 F.3d at 1372-73 (recognizing that voluntary dismissal with prejudice does not have issue preclusive effect).

infringement, validity, or enforceability of the Licensed Patents.” *Takeda*, 967 F.3d at 1348 n.5.<sup>8</sup>

There is no suggestion in the agreement that a voluntary dismissal – even with prejudice – would constitute an “adjudication” for the purposes of Section 1.2(d).

Takeda argues that the term “holding” cannot inform the understanding of the word “adjudicated” because that would result in circular reasoning such that the term “adjudicated” would no longer have any independent meaning. (D.I. 222 at 15). In other words, “holding” and “adjudicated” would have the same meaning. Mylan argues that the full context of Section 1.2(d) demonstrates that “holding” and “adjudicated” are not duplicative under its reading because “adjudicated” informs the scope of the relevant patents (i.e., only claims from three of the patents were adjudicated) whereas “holding” describes what the Final Court Decision must be (i.e., not infringed, etc.) to trigger the provision. (D.I. 226 at 7).

I agree with Mylan’s reading of the Agreement. Section 1.2(d) applies to all patent claims that were “asserted *and* adjudicated.” “Asserted” and “adjudicated” work together to define the scope of the patents relevant to Section 1.2(d). Neither term is duplicative of “holding,” which defines the outcome necessary to trigger Section 1.2(d). Consistent with the Federal Circuit’s affirmation, “[a] claim that was asserted but not adjudicated, or adjudicated but not asserted, is not

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<sup>8</sup> Takeda stated at oral argument that the Federal Circuit erred in its decision by not quoting the entire sentence in *Levi Strauss* regarding adjudication. (D.I. 242 at 11:13-16). The Federal Circuit did not misquote itself, but rather omitted the portion of the sentence stating that a stipulated dismissal with prejudice “operates as an adjudication on the merits for claim-preclusion purposes.” *See Takeda*, 967 F.3d at 1348 n.5. “[O]perates as” is used in this sentence because a dismissal with prejudice is not an adjudication and is not on the merits. But it is treated as something that it is not for the narrow purpose of claim preclusion. The remainder of the sentence that the Federal Circuit did quote is the pertinent portion, which states that “a stipulated dismissal with prejudice . . . ordinarily should not itself count as the actual adjudication of any issue.” *Id.*

relevant to Section 1.2(d).”<sup>9</sup> *Takeda*, 967 F.3d at 1347. Takeda’s decision tree does not persuade me otherwise.

## 2. “Holding”

Takeda argues that the five dismissed patents were not subject to a “holding” of “either (i) not infringed, or (ii) any combination of not infringed and invalid or unenforceable,” which follows from its contention that the asserted claims from the five dismissed patents were adjudicated. Mylan does not argue that there was a holding on those five patents. (D.I. 217 at 16-17). As explained above, because the five dismissed patents were not “asserted and adjudicated,” they are irrelevant to Section 1.2(d). The lack of any holding on those five patents does not prevent Section 1.2(d) from being triggered.

## 3. Gamesmanship

Takeda argues that it “cannot simply assert and drop patents on its own.” (D.I. 222 at 17). Takeda, however, admits that it can unilaterally assert and dismiss claims before a defendant files an answer or motion for summary judgment. (D.I. 222 at 17). In patent infringement cases with multiple asserted patents, it is common for defendants to move to dismiss a complaint before filing an answer, giving the plaintiff more time and opportunity to unilaterally dismiss claims before the defendant answers the complaint. Even after a defendant has answered the complaint, a plaintiff can seek a court order to dismiss its claims without defendant’s consent. .” FED. R. CIV. P. 41(a)(2). Indeed, the Third Circuit has set a liberal policy in favor of voluntary dismissals. *See In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 863 (3d Cir. 1990) (“Rule 41 motions should be allowed

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<sup>9</sup> Originally, Takeda took the position that all asserted patents had to be adjudicated, that it asserted eight patents against West-Ward and only three of them were adjudicated. *See Takeda*, 2020 WL 419488 at \*2. *See also Takeda*, 967 F.3d at 1348 (“Takeda has repeatedly and unequivocally stated that the five voluntarily dismissed patents were not adjudicated”). Takeda no longer makes that argument; it now argues the opposite.

unless defendant will suffer some prejudice other than the mere prospect of a second lawsuit.” (citations omitted)). Plaintiffs in patent cases routinely dismiss claims to narrow the issues as trial approaches and courts are generally willing to allow claims and patents to be dropped. In my experience, when a plaintiff moves to dismiss asserted claims with prejudice, no defendant objects.<sup>10</sup> When a plaintiff wants to dismiss one or more claims with prejudice and court approval is required, no judge hesitates to dismiss those claims with prejudice.

Takeda’s interpretation would give Takeda 100% control to make sure that Section 1.2(d) never applies. *Takeda*, 967 F.3d at 1346 (“[R]eading the License Agreement in this way leads to the absurd result that Takeda could prevent Mylan from ever relying on the clause by simply asserting and then withdrawing a claim from a proceeding.”). Such control would not even require anything approaching bad faith on Takeda’s part. Takeda could simply assert its 22 patents in litigation and withdraw or dismiss the weaker claims as the case moved along. Takeda would then be able to say the litigation was not a triggering event, no matter the final results on the patent claims taken to a decision, as Takeda could claim that the dismissed patents were “adjudicated” but not subject to a holding. This would be a strange interpretation, since the parties agree that the provision is in the Agreement to protect Mylan (D.I. 242 at 28:7-29:14) from events beyond its control (such as West-Ward winning its litigation). Takeda’s argument that it cannot withdraw asserted patents on its own such that it could prevent Section 1.2(d) from ever triggering is therefore unpersuasive.

### **C. Hatch-Waxman Act**

Takeda attempts to inject extrinsic evidence into the analysis, arguing that Section 1.2(d) was written with the Hatch-Waxman Act in mind. Takeda does not identify any industry practice

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<sup>10</sup> That’s why many such dismissals are stipulated.



or custom indicating similar agreements are read within the context of the Hatch-Waxman Act or FDA regulations. This regulatory backdrop is absent from the language of the provision and would not be understood by an objective, reasonable third party. *See Exelon*, 176 A.3d at 1267 (“[B]ecause Delaware adheres to an objective theory of contracts, the contract’s construction should be that which would be understood by an objective, reasonable third party.”).

Regardless, the context of the Hatch-Waxman Act fails to support Takeda’s interpretation. Takeda states that the parties necessarily agreed to a provision that “all asserted claims must be adjudicated to a ‘holding’” because of the backdrop of the Hatch-Waxman Act. (D.I. 222 at 18). This is simply not what the provision says. Takeda is attempting to rehash the same argument it made during the preliminary injunction proceedings that the provision is written with the intent of limiting Section 1.2(d) to litigation over generic Colcrys products. As explained in my prior order, and affirmed by the Federal Circuit, other sections of the Agreement showed the parties knew how to limit Mylan’s market entry based on whether a generic product was at issue. Section 1.2(d) makes no mention of generic Colcrys products, while Sections 1.2(b) and 1.2(f) do. The Agreement also defines a “Third Party” as a “Person other than a Party or an Affiliate of a Party” and is not limited to other generic manufacturers. If the parties wanted to limit Section 1.2(d) to litigation arising under the Hatch-Waxman Act, they could have done so. Instead, Section 1.2(d) is broader and other types of cases not related to the Hatch-Waxman Act, such as the *West-Ward* litigation, could trigger Section 1.2(d).

According to Takeda, Hatch-Waxman litigation requires that all asserted patents must be held either to be invalid or not infringed. (D.I. 222 at 17). In the absence of such a “holding,” there would be no substantive determination regarding patent infringement and the 30-month stay would not terminate. (*Id.* at 17–18). Thus, Takeda argues, a competitor to Mylan could engage in Hatch-

Waxman litigation, be successful, but if some of the asserted claims had been voluntarily dismissed “without a holding,”<sup>11</sup> the competitor would still be blocked by the 30-month stay while Mylan would not be. The argument does not work. The provision in the Agreement is to protect Mylan so that it is not outpaced by competitors, not the other way around. (D.I. 242 at 29:7-14). Mylan is under no obligation to concern itself with the effect of the provision on a third party. Takeda has also stipulated to dismissals without substantive determinations in Hatch-Waxman cases without concern about the 30-month stay. (*See* D.I. 227, Ex. 68 (resolving some asserted patents with covenants not to sue)). Takeda is free to enter into similar agreements with third parties if it is concerned about the outcome, but nothing in the Agreement contemplates the effect of Section 1.2(d) on third parties.

Because Section 1.2(d) of the Agreement is unambiguous and Mylan has shown that there is only one reasonable interpretation of the provision, it is unnecessary to examine the extrinsic evidence, including Takeda’s expert’s opinions, and summary judgment is proper.

#### **IV. CONCLUSION**

For the foregoing reasons, Defendant’s motion for summary judgment is GRANTED and Defendant’s motion to exclude expert testimony is DISMISSED as moot. An appropriate order will issue.

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<sup>11</sup> Takeda’s lead cite in support of this argument is described as a case involving a “dismissal without prejudice.” (D.I. 222 at 18).